

Food and Drug Administration, HHS

§ 880.6880

band stretched over long rollers that can advance itself under a patient and transfer the patient with minimal disturbance in a horizontal position to the stretcher.

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]

§ 880.6785 Manual patient transfer device.

(a) *Identification*. A manual patient transfer device is a device consisting of a wheeled stretcher and a mechanism on which a patient can be placed so that the patient can be transferred with minimal disturbance in a horizontal position to the stretcher.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38807, July 25, 2001]

§ 880.6800 Washers for body waste receptacles.

(a) *Identification*. A washer for body waste receptacles is a device intended for medical purposes that is used to clean and sanitize a body waste receptacle, such as a bedpan. The device consists of a wall-mounted plumbing fixture with a door through which a body waste receptacle is inserted. When the door is closed the body waste receptacle is cleaned by hot water, steam, or germicide.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice requirements of the quality system regulation

in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38807, July 25, 2001]

§ 880.6820 Medical disposable scissors.

(a) *Identification*. Medical disposable scissors are disposable type general cutting devices intended for medical purposes. This generic type of device does not include surgical scissors.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38807, July 25, 2001]

§ 880.6850 Sterilization wrap.

(a) *Identification*. A sterilization wrap (pack, sterilization wrapper, bag, or accessories, is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

(b) *Classification*. Class II (performance standards).

§ 880.6860 Ethylene oxide gas sterilizer.

(a) *Identification*. An ethylene gas sterilizer is a nonportable device intended for use by a health care provider that uses ethylene oxide (ETO) to sterilize medical products.

(b) *Classification*. Class II (performance standards).

§ 880.6870 Dry-heat sterilizer.

(a) *Identification*. A dry-heat sterilizer is a device that is intended for use by a health care provider to sterilize medical products by means of dry heat.

(b) *Classification*. Class II (performance standards).

§ 880.6880 Steam sterilizer.

(a) *Identification*. A steam sterilizer (autoclave) is a device that is intended for use by a health care provider to